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REMARKS

Status of the Claims

Claims 1-5 and 14-28 are pending in the application.

Claims 1-5 and 14-28 have been rejected.

By way of this reply and amendment, claims 1, 4, 16 and 21 have been amended, claims 19, 24 and 28 have been canceled, and new claims 29-34 have been added.

Upon entry of this amendment, claims 1-5 and 14-18, 20-23, 25-27 and 29-34 will be pending.

Summary of the Amendment

Claims 1 and 4 have been amended to refer the step of obtaining isolated Vpr protein or fragments thereof prior to administering Vpr or fragments thereof to cells. Support for this amendment is found throughout the claims as originally filed and the specification, such as on page 12, line 23 to page 16, line 10. No new matter has been added.

Claims 1 and 4 have also been amended to delete reference to the use of nucleic acid molecules that Vpr protein or fragments thereof, which correspond to the previously held patentably distinct invention set forth in Group II.

Claims 16 and 21 have been amended to be in independent. Claims 16 and 21 refer the step of obtaining isolated Vpr protein prior to administering Vpr to cells.

New claims 29-34 refer to methods of inhibiting lymphocyte activation. Support for new claims. Support for this amendment is found throughout the claims as originally filed and the specification, such as on page 10, lines 14-20. No new matter has been added.

Rejection under 35 U.S.C. §112, first paragraph

Claims 1-5 and 14-28 have been rejected under 35 U.S.C. §112, first paragraph, because, it is asserted, the specification, while enabling for inhibiting proliferation and preventing activation of T cells with full length Vpr protein, does not reasonably provide enablement for inhibiting proliferation and preventing activation of T cells with a fragment of Vpr protein.

Applicants note that claims 16-20 refer to embodiments of claim 1 which refer to the full length Vpr protein, while claims 21-24 refer to embodiments of claim 4 which refer to the full length Vpr protein. Further, claims 17 and 22 further limit claims 16 and 21, respectively, to T cells. Accordingly, while the rejection has been made to each of the pending claims, only claims 1-4, 14, 15 and 25-28 refer to fragments of Vpr.

It is well settled that an enablement rejection include reasoning and evidence to doubt the objective truth of an applicant's assertion that the claims are enabled. The burden initially lies with the Patent Office. In the absence of reasoning and evidence in support of an enablement rejection, an enablement rejection is improper. When reasoning ands evidence is provided, the evidence of record must be viewed as whole to determine if one skilled in the art would conclude the claims are not enabled.

With respect to the support for the rejection contained in the Official Action, the only evidence and reasoning provided the reference to certain data reported in Rogel et al. Rogel et al describe infection of cultured T cells and PBMCs with HIV strains that either have wild type Vpr gene (Vpr+) or a truncated Vpr gene that expresses a 45 amino acid protein (Vpr-). Rogel et al. reports that the cells infected with Vpr- virus proliferated more than the cells did when infected with Vpr+ virus. It is asserted that this reference supports the conclusion that functional fragments of Vpr are not enabled.

Applicants respectfully urge that those skilled in the art viewing Rogel would not conclude that all fragments of Vpr would not have the inhibition of cell proliferation function

of wild-type Vpr. On the contrary, those skilled in the art would expect there to be functional fragments of Vpr and disclosure of a single non-functioning fragment would not lead them to conclude that all fragment of Vpr are non-functioning or that the identification of functional fragments would require undue experimentation. In re Wands, which was cited in the Official Action, makes clear that experimentation is permissible as long as it is not undue. It would not be undue experimentations to identify functional fragments of Vpr and nothing in Rogel would lead one skilled in the art to conclude that it would be.

When the evidence of record is considered in its totality, those skilled in the art would not question the objective truth of Applicants' assertion of enablement.

With regard to claims 16-24, which each include the limitation that a full length Vpr protein is used, no evidence or reasoning has been provided to doubt the objective truth of Applicants' assertion of enablement. The rejection is wholly unsupported.

Applicants respectfully request that the rejection of claims 1-4 and 14-28 under 35 U.S.C. §112, first paragraph, be withdrawn.

Rejection under 35 U.S.C. §102(a)

Claims 1-5 and 14-28 have been rejected under 35 U.S.C. §102(a) as being anticipated by Rogel et al.

Rogel et al describe infection of cultured T cells and PBMCs with HIV strains that either have wild type Vpr gene (Vpr+) or a truncated Vpr gene that expresses a 45 amino acid protein (Vpr-). Infection with Vpr- contained resulted in higher cell numbers of infected cells post infection compared to cell numbers in Vpr+ infected cultures. Rogel et al. also discloses experiments in which expression of the Vpr gene in cultured human embryonic kidney 293T cells resulted in an alteration of the cell cycle distribution of the cultured cells. it is asserted in the Official Action that the experiments using cultured T cells show Vpr inhibits T cell proliferation and activation.

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Applicants respectfully urge that the claims are not anticipated by Rogel et al.

The claims have been amended to add reference to obtaining isolated Vpr and to delete reference to the use of nucleic acid molecules encoding Vpr protein. Rogel et al. shows administering virus or plasmids that include Vpr genes. Rogel et al. neither teaches nor suggests administering Vpr protein following its isolation. As noted in the previous Official Action, the use of the Vpr gene is patentably distinct from the use of the protein.

Rogel et al. does not teach or suggest the effect on it by Vpr on lymphocyte activation. Rogel et al. does not teach or suggest administering Vpr protein following its isolation in order to prevent or inhibit lymphocyte activation.

Applicants respectfully request that the rejection of claims 1-5 and 14-28 under 35 U.S.C. §102(a) as being anticipated by Rogel et al. be withdrawn.

Conclusion

Claims 1-5 and 14-18, 20-23, 25-27 and 29-34 are in condition for allowance. An early indication of allowability and notice of allowance is earnestly solicited.

As indicated on the transmittal accompanying this response, the Commissioner is hereby authorized to charge any debit or credit any overpayment to Deposit Account No. 50-1275.

Respectfully submitted,

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